



PRESS RELEASE

Attorney General Announces \$60 Million Multistate Settlement with C.R. Bard, Inc.

BALTIMORE, MD (September 24, 2020) – Maryland Attorney General Brian E. Frosh today announced a [settlement](#) by 48 states and the District of Columbia with C.R. Bard, Inc. and its parent company Becton, Dickinson and Company requiring payment of \$60 million for the deceptive marketing of transvaginal surgical mesh devices.

Surgical mesh is a synthetic knitted or woven fabric that is permanently implanted in the pelvic floor through the vagina to treat pelvic organ prolapse and stress urinary incontinence. These are common conditions faced by women due to a weakening in their pelvic floor muscles caused by childbirth, age, and other factors.

Thousands of women implanted with surgical mesh have reported that they suffered serious complications resulting from these devices, including chronic pain, erosion of mesh through organs, pain during sexual intercourse, and voiding dysfunction. Although the attorneys general allege that use of surgical mesh involves the risk of these serious complications and is not proven to be more effective than traditional tissue repair, millions of women were implanted with these devices.

The attorneys general allege that C.R. Bard misrepresented or failed to adequately disclose serious and life-altering risks of surgical mesh devices, such as chronic pain, scarring and shrinking of bodily tissue, painful sexual relations, and recurring infections, among other complications.

“Manufacturers of medical devices must inform physicians and patients of the risks their products pose. Thousands of women suffered infections, pain and incontinence, because they were unaware of the risks of transvaginal mesh,” said Attorney General Frosh. “This settlement requires the disclosure of important risk information to patients and doctors.”

C.R. Bard and its parent company, Becton, Dickinson and Company, have agreed to pay \$60 million to the 48 participating states and the District of Columbia. Although C.R. Bard stopped selling transvaginal mesh, the settlement provides injunctive relief, requiring both C.R. Bard and Becton, Dickinson and Company to adhere to certain injunctive terms if they reenter the transvaginal mesh market.

Under the terms of the settlement, the companies are required to:

- In all marketing materials that address complications and in its instructions for use, include a list of certain risks, such as:
 - Pelvic pain, which in some patients may not resolve;
 - Pain with intercourse, which in some patients may not resolve;
 - Erosion;
 - Exposure of mesh material into the vagina, which can be associated with pain during intercourse for the woman and/or her partner;
 - Pain caused by exposure may be severe and may result in permanent sexual dysfunction;
 - Infection;
 - Voiding dysfunction, including new-onset urge incontinence;
 - Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur; and
 - That correction of mesh-related complications may involve multiple surgeries, but additional surgeries may not resolve complications, and that complete removal of mesh may not be possible.
- In patient marketing materials, put risk information in terms that are understandable to patients.
- Refrain from misrepresenting the extent to which certain risks are common to all pelvic floor or other surgeries.
- Refrain from representing in marketing materials that certain risks can be eliminated with surgical experience or technique alone.
- Refrain from representing in marketing materials that certain mesh is “soft” or has “multidirectional elasticity” within the body after implantation.
- Disclose complications related to the use of mesh in any training provided that includes risk information.
- Train independent contractors, agents, and employees who sell, market, or promote mesh regarding their obligations to report all patient complaints and adverse events to the company.

Attorney General Frosh’s office helped to lead this investigation and settlement negotiation.